DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0036]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Possible Footnotes and Cueing Schemes to Help Consumers Interpret Quantitative Trans Fat Disclosure on the Nutrition Facts Panel

71 FR 6079
2/6/06

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on an experimental study of possible footnotes and cueing schemes intended to help consumers understand and apply quantitative *trans* fat information they might see on the Nutrition Facts Panel of a food product. The experimental study will estimate the communication effectiveness of quantitative *trans* fat information in terms of its ability to help consumers make heart-healthy product decisions in realistic label usage situations for a range of products.

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DATES: Submit written or electronic comments on the collection of information by [*insert date 60 days after date of publication in the* **Federal Register**]. Comments due 4/7/06

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether

the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Experimental Study of Possible Footnotes and Cueing Schemes to Help Consumers Interpret Quantitative *Trans* Fat Disclosure on the Nutrition Facts Panel (OMB Control Number 0910–0532)—Reinstatement

FDA is requesting OMB approval of an experimental study of possible footnotes and cueing schemes intended to help consumers interpret quantitative *trans* fat information on the Nutrition Facts Panel of a food product. The purpose of the experimental study is to help FDA's Center for Food Safety and Applied Nutrition formulate decisions and policies affecting labeling requirements for *trans* fat disclosure.

In the **Federal Register** of July 11, 2003 (68 FR 41434), FDA issued a final rule requiring disclosure on the Nutrition Facts Panel of quantitative *trans* fat information on a separate line without any accompanying footnote. At the same time, the agency issued an advance notice of proposed rulemaking entitled, "Food Labeling: *Trans* Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements," (68 FR 41507) which requested comments about possible footnotes to help consumers better understand *trans* fat declarations on the product label. The agency sought comments about whether it should consider requiring statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote on the Nutrition

Facts Panel to enhance consumers' understanding about such cholesterol-raising lipids and how to use information on the label to make healthy food choices. Comments received in response to the notice contained suggested footnotes and cueing schemes. The proposed experimental study will evaluate the ability of several possible footnotes and cueing schemes to help consumers make heart-healthy food choices. The results of the experimental study will provide empirical support for possible policy decisions about the need for such requirements and the appropriate form they should take.

FDA or its contractor will use information gathered from Internet panel samples to evaluate how consumers understand and respond to possible footnote and cueing schemes. The distinctive features of Internet panels for the purpose of the experimental study are that they allow for controlled visual presentation of study materials, experimental manipulation of study materials, and the random assignment of subjects to condition. Experimental manipulation of labels and random assignment to condition makes it possible to estimate the effects of the various possible footnotes and cueing schemes while controlling for individual differences between subjects. Random assignment ensures that mean differences between conditions can be tested using well-known techniques such as analysis of variance or regression analysis to yield statistically valid estimates of effect size. The study will be conducted from a sample drawn from a large, nationally representative consumer panel with 800,000 households. The sample size and population pool are adequate to ensure that results can be generalized.

Participants will be adults, age 18 and older, who are recruited for a study about foods and food labels. Each participant will be randomly assigned to

one of the 42 experimental conditions derived from fully crossing 7 possible footnotes/cueing schemes, 3 product types, and 2 prior knowledge conditions.

FDA will use the information from the experimental study to evaluate regulatory and policy options. The agency often lacks empirical data about how consumers understand and respond to statements they might see in product labeling. The information gathered from this experimental study will be used to estimate consumer comprehension and the behavioral impact of various footnotes and cueing schemes intended to help consumers better understand quantitative *trans* fat information.

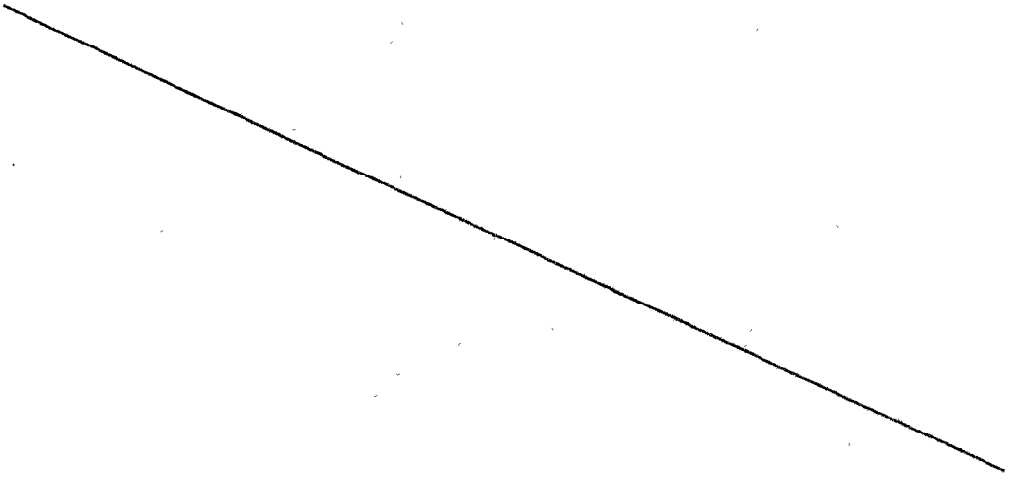
The experimental study data will be collected using participants of an Internet panel of approximately 600,000 people. Participation in the experimental study is voluntary.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Type of Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Internet survey	3,240	1	3,240	.25	810
Total					810

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.



FDA's burden estimate is based on prior experience with Internet panel experiments similar to the study proposed in this document.

Dated: JAN 30 2006

January 30, 2006.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 06–????? Filed ??–??–06; 8:45 am]

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